



Public Health England

Protecting and improving the nation's health

PHE Gateway Number: 2018255

For action:

NHS England Regional Directors and Directors of Commissioning Operations
NHS England/ Public Health England Screening and Immunisation Leads
Clinical Commissioning Groups Clinical Leaders and Accountable Officers
General Practitioners
Local Medical Committees
Local Authority Chief Executives and Directors of Public Health
Heads of Midwifery
Paediatricians
TB Services
NHS England Occupational Health Leads

For information:

DHSC
MHRA
Chief Pharmacists of NHS Trusts
NHS Specialist Pharmacy Service
Royal College of Paediatrics and Child Health
Royal College of Midwives
Royal College of Physicians
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists
Royal College of General Practitioners

12 July 2018

Dear Colleague,

Important update on supply of UK-licensed BCG vaccine manufactured by AJ Vaccines (formerly the Statens Serum Institut (SSI)) for the national BCG programme

The purpose of this letter is to advise you that AJ Vaccines has resumed supply of the sole UK-licensed BCG vaccine to Public Health England's (PHE's) central stockholding.

BCG Vaccine Supply

BCG vaccine is centrally supplied by PHE to the NHS in line with national policy to selectively offer vaccination to those at increased risk of exposure to tuberculosis infection.

Since 2015, supply of the only UK-licensed BCG vaccine into the UK from the contracted supplier, SSI, was interrupted due to manufacturing issues. In turn, this led to ordering restrictions and advice being issued on priority groups for BCG vaccine.

From June 2016, an alternative BCG vaccine from InterVax Ltd was supplied to enable the continuation of the programme. Alongside this PHE issued guidance and training materials to healthcare professionals on the administration of the vaccine, and information for parents and carers.

It is anticipated that PHE will be in a position to re-open ordering for the UK-licensed AJ Vaccines product in late July or August 2018. In the meantime, PHE will continue to make available Intervax BCG vaccine for ordering through the ImmForm website.

All organisations holding centrally supplied BCG vaccine are asked to use their current stocks of Intervax BCG vaccine **before** ordering AJ Vaccines BCG Vaccine to minimise vaccine wastage. This is particularly important as supplies for this vaccine remain globally constrained.

Licensed BCG vaccine (AJ Vaccines)

BCG vaccine supplied by AJ Vaccines is presented as a powder for reconstitution in a glass vial with synthetic stopper. Each pack ordered contains 10 vials. One vial of reconstituted vaccine contains 1 ml, corresponding to 10 doses (of 0.1 ml) for adults and children aged 12 months and over or 20 doses (of 0.05 ml) for infants under 12 months of age.

PHE is developing a national PGD for the administration of BCG vaccine manufactured by AJ Vaccines. In the event that this licensed vaccine is available before a PGD is published, provider organisations should continue to use PSDs in the interim.

Ensuring all eligible groups can access BCG vaccine

PHE anticipates having sufficient BCG vaccine for all eligible groups. To help with managing this, ordering will be opened to all ImmForm account holders at an initial 2 packs per order per week (each pack contains up to 200 infant doses). This order restriction will be kept under review. To note, that at times the shelf life of this product may be relatively short, therefore it is advised not to create locally held stockpiles. In the event that further packs are required, please contact Helpdesk@immform.org.uk.

In line with previous communications¹, NHS England commissioners, Screening and Immunisation Teams and Clinical Commissioning Groups are asked to work together to

¹ Vaccine Update Issue 265, July 2017

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/625783/VU_bcg_july2017.pdf

ensure that eligible children aged 1 to 5 years who missed out on the vaccine during the period of constrained supply are caught up as soon as is practicable.

Information materials for health professionals and the public

Further information for healthcare workers on the use of licenced vaccine will be available on the Gov.UK website shortly:

<https://www.gov.uk/government/collections/immunisation#tuberculosis>

The Tuberculosis chapter of Immunisation against infectious disease (the “Green Book”) is being revised and will be published in due course.

Further updates on the BCG programme will be published in Vaccine Update:

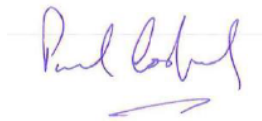
<https://www.gov.uk/government/collections/vaccine-update#2018>

Subscribe to Vaccine Update newsletter here:

<https://public.govdelivery.com/accounts/UKHPA/subscribers/new?preferences=true>

If you have any queries about the content of this letter please contact immunisation@phe.gov.uk.

Yours faithfully,

A handwritten signature in blue ink that reads "Paul Cosford". Below the signature is a horizontal line with an arrow pointing to the right.

Professor Paul Cosford
Director for Health Protection and
Medical Director
Public Health England